Environmental Assessment

1. Date	September 28, 2015
2. Name of Applicant	Brainerd Chemical Company
3. Address	Agent for Notifier: Mitchell Cheeseman, Ph.D. Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) in the production and preparation of whole or cut poultry and meat.

When used as intended, the components of the FCS mixture will not exceed:

(1) 2000 ppm peroxyacetic acid (PAA), 730 ppm hydrogen peroxide (HP), and 14 ppm 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) in spray, wash, rinse, dip, chiller water, low-temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs; and

(2) 1800 ppm PAA, 655 ppm HP, and 12.0 ppm HEDP in process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including carcasses, parts, trim, and organs.

b. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food or in the process water or ice used during production. Use of the FCS helps to retard the spoilage of the food and prevent cross-contamination, ultimately providing for safer foods for consumers.

In summary, the requested action to expand the currently approved uses of the FCS is needed to address current and future needs of meat and poultry processors and governmental agencies to improve food safety. Use of the FCS provides more options for antimicrobial interventions. For example, the use of peroxyacetic acid at higher concentrations for relatively short periods of time, and in smaller total volumes, enhances the capacity of the food industry to improve processing techniques, such as providing more flexibility in terms of time, concentrations, application method (spray vs. immersion) to better control food pathogens. More recently, the USDA has imposed additional testing for the poultry industry for *Campylobacter spp*. For many processing plants it has been found that an additional treatment using higher concentrations of peroxyacetic acid (400-2000 ppm) for a short period of time (seconds) can result in satisfactory reduction of this new species of pathogen that is now part of routine testing.

The USDA is also looking to expand testing to more areas of processing, to other meats, and also to newer species of bacteria, such as Shiga Toxin-Producing *Escherichia coli* (STEC).

The FCS is intended for use as an antimicrobial solution for use in the processing of meat and poultry. This notification requests an increase in the at-use levels of the FCS, which is the subject of previously authorized FCNs. The increased levels are necessary to accomplish greater reductions in microbial load.

c. Locations of Use/Disposal

The antimicrobial agent is intended for use in meat and poultry processing plants and packing and storage facilities throughout the United States. It is expected that on-site waste water treatment facilities will discharge to publically owned treatment works (POTW) but we have also considered discharge to surface waters. Although we do not expect application of sludge from wastewater treatment facilities to soil, we have also estimated maximum potential concentrations in soil from this route of disposal.

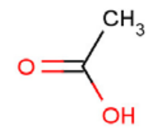
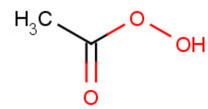
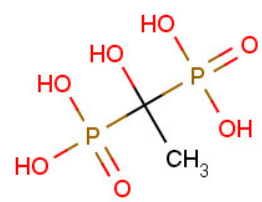
In poultry processing facilities the antimicrobial will be applied to the surfaces of poultry carcasses, parts, organs or trim by an immersion dip and/or a spray cabinet. Typically, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a “main chiller” bath, as well as a “finishing chiller” bath, both containing the FCS. After the diluted product is sprayed onto the poultry, or the poultry is unloaded out of an immersion dip, the bulk of the solution drains off of the product. The waste solution ultimately runs into drains and enters the poultry processing plant water treatment facility. All of this water is collected and treated by the facility prior to it being sent to a POTW. Very minor quantities are lost to evaporation.

In meat processing facilities the product is applied to the surface of meat carcasses or parts by spraying the carcasses that are suspended on a moving conveyor line or rail system. The system carries the carcass into a spray cabinet, in which spray nozzles are distributed in a manner that ensures even application of the dilute FCS solution onto the surface of the carcass. The carcass exits the other side of the spray cabinet and continues on the processing line. In some instances, meat parts are placed in a dip tank containing this product, diluted to an appropriate intervention treatment concentration, in order to ensure full contact with the intervention treatment. After the diluted product is applied to the carcass, the majority of the product drains off of the meat and ultimately runs into drains and enters the meat processing plant water treatment facility prior to it being sent to a POTW. Very minor quantities are potentially lost to evaporation.

5. Identification of Substances that are Subject of the Proposed Action

The raw materials used in this product are hydrogen peroxide, acetic acid, HEDP, and water. Peroxyacetic acid formation is the result of an equilibrium reaction between hydrogen peroxide and acetic acid. The FCS is supplied in concentrated form and is diluted at the processing plant for use to achieve the desired level of peroxyacetic acid that is needed to address the microbial load.

Table 1: Chemical Identity of Substances of the Proposed Action

Component	CAS No.	Molecular Weight	Structural Formula	Molecular Formula
Hydrogen peroxide	7722-84-1	34.01	HO-OH	H_2O_2
Acetic acid	64-19-7	60.05		$C_2H_4O_2$
Peroxyacetic acid	79-21-0	76.05		$C_2H_4O_3$
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	2809-21-14	206.3		$C_2H_8O_7P_2$
Water	7732-18-5	18.01	H-O-H	H_2O

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable federal, state and local environmental regulations. Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Introduction of dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water and spray application onto meat and poultry, and the subsequent disposal of such water and spray drainage into on-site treatment plants and/or POTWs. The total amount of product used at a typical facility will vary significantly, depending on the equipment used and the amount of meat and poultry processed. The maximum at-use concentration of PAA, hydrogen peroxide, and HEDP for each application will be as follows:

Table 2: Summary of Intended Uses

Use	PAA	H_20_2	HEDP
Process water or ice used for washing, rinsing, storing, or cooling whole or cut meat, including carcasses, parts, trim, and organs	1800 ppm	655 ppm	12 ppm
Spray, wash, rinse, dip, chiller water, low-temperature (e.g., less than 40°F) immersion baths, or scald water for whole or cut poultry carcasses, parts, trim, and organs	2000 ppm	730 ppm	14 ppm

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in complete degradation of PAA, hydrogen peroxide, and acetic acid. Specifically, the PAA will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water.[1] All three compounds are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. The half-life of PAA in buffered solutions was 63 hours at pH 7 for a 748 ppm solution, and 48 hours at pH 7 for a 95 ppm solution.[2] The half-life of hydrogen peroxide in natural river water ranged from 2.5 days when initial concentrations were 10,000 ppm, and increased to 15.2 days and 20.1 days when the concentration decreased to 250 ppm and 100 ppm, respectively.[3] In biodegradation studies of acetic acid using activated sludge, 99% degraded in 7 days under anaerobic conditions.[4] Acetic acid is not expected to concentrate in the wastewater discharged to the treatment facility/POTW. Therefore, these substances are not expected to be introduced into the environment to any significant extent as a result of the proposed use of the FCS. As a result the remainder of this section will consider only the environmental introduction of HEDP.

[1] U.S. Environmental Protection Agency, *Reregistration Eligibility Decision: Peroxy Compounds* (December 1993), p. 18, available at http://www.epa.gov/pesticides/reregistration/REDs/old_reds/peroxy_compounds.pdf.
[2] European Centre for Toxicology and Toxicology of Chemicals (ECETOC), *Joint Assessment of Commodity Chemicals (JACC) No. 40 Peracetic Acid and its Equilibrium Solutions*, January 2001, Table 11, p. 29, available at http://www.ecetoc.org/jacc-reports.
[3] ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993, Table 6, p. 23, "Degradation in the River Soane of Hydrogen Peroxide," available at http://www.ecetoc.org/jacc-reports.
[4] American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001, Appendix 1, p. 1, available at http://www.epa.gov/HPV/pubs/summaries/acetisalt/c13102tp.pdf..

i. Poultry Processing Facilities

Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water and spray application onto poultry carcasses, parts, organs, and trim, and the subsequent disposal of such water and spray drainage into the processing plant wastewater treatment facility. In poultry processing facilities, the defeathered, eviscerated carcasses are generally sprayed before being chilled via submersion in baths. The carcass is carried on a conveyor through a spray cabinet and then submerged in the chiller baths. Parts and organs may also be chilled by submersion in baths containing the antimicrobial agent. Chiller baths typically include a "main chiller" bath and a "finishing chiller" bath, both containing the FCS.

When the FCS is used at the maximum level under the proposed action, HEDP would be present in water at a maximum level of 14 parts per million (ppm). Water is used in poultry processing for scalding (feather removal), bird washing before and after evisceration, chilling, cleaning and sanitizing of equipment and facilities, and for cooling of mechanical equipment such as compressors and pumps.[5] Many of these water uses will not utilize the FCS, resulting in significant dilution of HEDP into the total water effluent. Assuming, in the very worst-case, that all of the water used in a poultry processing plant is treated with the FCS, the level of HEDP in water entering the plant's wastewater treatment facility, the environmental introduction concentration (EIC), would be 14 ppm.

ii. Meat Processing

In meat processing operations, process water containing the diluted FCS is sprayed directly on to the exposed surfaces of whole carcasses or cuts of meat. The vast majority of the solution sprayed onto the carcasses drains off the meat and enters the facility's water treatment system. Although the FCS may be used in contact with all types of meat, including pork, venison, and mutton/lamb, its use in the processing of beef constitutes the largest sector of the meat processing industry in terms of market share. The processing of pork is the sector that is expected to generate the largest amount of effluent.[6]

Although the total water usage may differ between beef and pork processing plants, when the FCS is used in either application the maximum at-use concentration of HEDP in the wash water is limited to 12 ppm. Water is used in meat processing facilities for purposes other than carcass and meat washing (i.e. for cleaning, boiler water, cooling waters, etc.). This additional water use will dilute the concentration of HEDP in the total water effluent to lower levels. Indeed, these other uses are reported to account for approximately 60% of the total water used in a hog slaughterhouse.[7] Based on this information, it is conservative to utilize a dilution factor of

[5] U.S. Environmental Protection Agency, *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, September 8, 2004, p. 6-7, available at http://water.epa.gov/scitech/wastetech/guide/mpp/upload/2008_07_15_guide_mpp_final_tdd06.pdf.

[6] *Id*., Table 6-3, "Characteristics of Wastewater Generated at Two Hog and Three Cattle Processing Facilities," p. 6-6.

[7] Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006, Figure 3.2, p. 71 (summing values from the personal hygiene (~9%), cooling water (5%), knife sterilizing (5%), lairage washing (~3%), vehicle washing (~4%), and cleaning (~32%) categories, and assuming that all of the sprays and rinses are used during processing).

one-half for both pork and beef processing facilities. We therefore estimate the maximum amount of HEDP entering a facility's wastewater treatment plant as a result of the requested use of the FCS (the EIC) in pork or beef processing facilities would be 6.0 ppm.

In sum, as large-scale facilities do not typically process more than one type of animal, we will use the calculated EIC for poultry of 14 ppm as the worst-case concentration for all meat and poultry facilities using the FCS.

7. Fate of Emitted Substances in the Environment

HEDP will slowly degrade to carbon dioxide, water and phosphates. Phosphate anions are strongly bound to organic matter and soil particles, and phosphate is a required macronutrient of plants. However, given the maximum level estimated to be released, we would not expect that phosphate released from HEDP would result in measurable increases in phosphate in soil or water receiving treated effluent. Decomposition of HEDP occurs at a moderately slow pace; a Dissolved Organic Carbon removal of 23-33 % after 28 days was observed in an inherent biodegradability test (Zahn-Wellens test).[8] Therefore, increases in phosphate in soils amended with wastewater sludge, or in water receiving treated effluent are not expected.

The Human and Environmental Risk Assessment Project (HERA) report on phosphonates indicates that the treatment steps at an onsite wastewater treatment facility or POTW will remove at least a portion of any HEDP in the process water.[9] The HERA report cites 80% adsorption of HEDP to sewage treatment sludge. We have estimated the potential environmental introductions of HEDP in water and sewage sludge applying the 20:80 partition factor from the HERA report. (See Table 3 below).

Table 3: Worst-case EICs for HEDP Using Poultry Processing as the Worst Case

Use	EIC Total	EIC_{sludge}	EIC_{water}
Poultry	14.0 ppm	11.2 ppm[10]	2.8 ppm[11]

When the water from the facility treatment plant or POTW is discharged to surface waters, it will be diluted a further 10-fold, resulting in an estimated environmental concentration of 0.28 ppm.[12] Finally, we note that the EIC for sludge is a maximum for terrestrial impacts, as any sludge used as a soil amendment will likely be significantly diluted by soil or sludge form other sources.

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[8] HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8)*, Draft 06/09/2004, Table 7, p. 16, available at http://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf.
[9] *Id.*, at Table 12, p. 22.
[10] Example Calculation 14.0 ppm*80% = 11.2 ppm
[11] Example Calculation 14.0 ppm*20% = 2.8 ppm
[12] Rapaport, R.A., *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*, Environmental Toxicology and Chemistry 7(2), 107-115 (1988), available at http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract.

8. Environmental Effects of Released Substances

a. Terrestrial Toxicity

The HERA report discusses biodegradation of HEDP and estimates a half-life in soil of 373 days. Therefore HEDP is expected to degrade, albeit slowly, in soil. HEDP shows no toxicity to terrestrial organisms at levels up to 1000 mg/kg soil dry weight (No Observed Effect Concentration; NOEC).[13] Our maximum estimated concentration in sludge (11.2 ppm) is orders of magnitude smaller than the NOEC and the maximum concentration in soil when used as a soil amendment should have an even larger margin of safety with respect to the NOEC. Therefore, the FCS is not expected to have any terrestrial environmental toxicity concerns at levels at which it is expected to be present in sludge or soil. Moreover, the much smaller level of HEDP present in the surface water is not expected to have any adverse environmental impact with respect to sedimentation based on the terrestrial toxicity endpoints available for plants, earthworms, and birds.[14]

b. Aquatic Toxicity

Aquatic toxicity of HEDP has been summarized, and is showing in the following table:

Table 4: Summary of Environmental Toxicity Data for HEDP[15]

Species	Endpoint	mg/L
Short Term		
Lepomis macrochirus	96 hr LC_{50}	868
Oncorhynchus mykiss	96 hr LC_{50}	360
Cyprinodon variegatus	96 hr LC_{50}	2180
Ictalurus punctatus	96 hr LC_{50}	695
Leuciscus idus melonatus	48 hr LC_{50}	207 – 350
Daphnia magna	24 – 48 hr EC_{50}	165 – 500
Palaemonetes pugio	96 hr EC_{50}	1770
Crassostrea virginica	96 hr EC_{50}	89
Selenastrum capricornutum	96 hr EC_{50}	3
Selenastrum capricornutum	96 hr NOEC	1.3
Algae	96 hr NOEC	0.74
Chlorella vulgaris	48 hr NOEC	≥100
Pseudomonas putida	30 minute NOEC	1000
Long Term		
Oncorhynchus mykiss	14 day NOEC	60 – 180

[13] Jaworska, J., et al, *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002.
[14] *Id.*
[15] Short term values for *Lepomis macrochirus*, *Oncorhynchus mykiss*, *Cyprinodon variegatus*, *Ictalurus punctatus*, *Leuciscus idus melonatus*, *Daphnia magna*, *Palaemonetes pugio*, *Crassostrea virginica*, *Chlorella vulgaris*, *Pseudomonas putida*, and long term values for *Oncorhynchus mykiss*, *Daphnia Magna* found in Jaworska, et al, p. 662 (2004). Short term values for *Selenastrum capricornutum*, and short and long term values for algae found in HERA (2004) (Tables 13 and 14, p. 29-31).

Daphnia Magna	28 day NOEC	10 – <12.5
Algae	14 day NOEC	13

According to Jaworska et al,[16] the primary adverse effects of HEDP result from chelation of nutrients rather than direct toxicity of HEDP. Chelation is not toxicologically relevant in the current evaluation because eutrophication, not nutrient depletion, has been demonstrated to be the controlling toxicological mode when evaluating wastewater discharges from food processing facilities. The lowest short-term LC_{50} values published for *Selenastrum capricornutum* (3 ppm), *Daphnia magna* (165 ppm), and *Crassostrea virginica* (89 ppm) are acute toxicity endpoints considered to result from this chelation effect. These values are not relevant when excess nutrients are present as expected in food processing wastewaters. The lowest relevant endpoint for food processing uses was determined to be the chronic NOEC of 10 ppm for *Daphnia magna*. Although uncertainties intrinsic to its derivation make the usefulness of the NOEC debatable,[17] based on the available environmental toxicology data, reliance upon the NOEC for *Daphnia magna* is appropriate.[18] The EEC of 0.28 ppm is approximately 35-fold lower than the 10 ppm chronic NOEC for *Daphnia magna*.

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the components readily degrade. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no environmental impact.

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[16] Jaworska, et al (2004).
[17] Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995, chapter 27 ("NOEC determinations are likely more statistically variant (uncertain) than EC_{50} determinations"); also see Organisation for Economic Co-operation and Development (OECD), *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 54, Environment Directorate, Paris, 2006 (recommending that that NOECs be abandoned), available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2006)18&doclanguage=en.
[18] Jaworska, et al (2004).

The addition of the antimicrobial agent to the options available to food processers is not expected to increase the use of peroxyacetic acid antimicrobial products.

12. List of Preparers

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Ms. Attwood has six years of experience preparing environmental submissions to FDA for the use of peroxyacetic acid antimicrobials.

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011 including oversight of FDA's initial NEPA review for the regulations implementing the Food Safety Modernization Act.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: September 28, 2015

Mitchell Cheeseman, PhD

14. References

American Chemistry Council, Acetic Acid and Salts Panel, *U.S. High Production (HPV) Chemical Challenge Program: Assessment Plan for Acetic Acid and Salts Category*, June 28, 2001.

Blok J. and Balk F., *Environmental regulation in the European Community*, in Fundamentals of Aquatic Toxicology: Effects, Environmental Fate, and Risk Assessment, (GM Rand, Ed.), Taylor & Francis, New York, 1995.

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ECETOC, *JACC No. 22, Hydrogen Peroxide*, January, 1993.

HERA, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products, *Phosphonates (CAS 6419-19-8; 2809-21-4; 15827-60-8)*, Draft 06/09/2004.

Jaworska, J., et al, *Environmental risk assessment of phosphonates, used in domestic industry and cleaning agents in the Netherlands*, Chemosphere 2002, 47(6), 655-665, May 2002.

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Rapaport, R.A., *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*, Environmental Toxicology and Chemistry 7(2), 107-115, 1988.

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U.S. Environmental Protection Agency, *Technical Development Document for the Final Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category (40 CFR 432)*, EPA-821R-04-011, September 8, 2004.

Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*, 2006.

15. Attachments